MAY - 3 2000

K001083

a. Summary Of Safety And Effectiveness

Contact Person

Jim Leathley
Senior Regulatory Affairs Specialist
Boston Scientific / Target
47900 Bayside Parkway
Fremont, CA. 94538

Trade Name

Guglielmi Detachable Coil (GDC), Class III

Common Name

Occlusion Coil

Classification Name

Artificial Embolization Device (21 CFR Section 882.5950)

Predicate Devices

Number	Description	Predicate for	Clearance Date
K991139 (Boston Scientific / Target)	Guglielmi Detachable Coil (GDC) System with Version 4 Modifications	Additional GDC 4 modifications that are the subject of this Special 510(k)	22 Dec. 1999

Intended Use

GDC Power Supply

Boston Scientific/Target's Guglielmi Detachable Coil (GDC) Power Supply is intended for use with all versions of Boston Scientific/Target's Guglielmi Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

Guglielmi Detachable Coil

The Guglielmi Detachable Coil (GDC) is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:
a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

Device Description

The GDC system consists of

- GDC power supply
- GDC occlusion coil attached to a delivery wire
- set of GDC connecting cables
- patient return electrode
- two 9-volt batteries

each of which is sold separately.

The occlusion coil is detached by electrolytically dissolving a small portion of the delivery wire upon desired placement of the coil in the anatomy.

GDC occlusion coils are manufactured from platinum wire which is first wound into a primary coil and then formed into a secondary helical shape.

Coils are attached to a delivery wire, which consists of a ground stainless-steel core wire with a stainless-steel coil welded at the distal end and a Teflon® outer jacket. The delivery wire is similar to that employed for the predicate GDC cleared under K991139.

The GDC Power Supply is a battery-operated, self-contained unit designed to initiate and control the electrolytic detachment of a GDC coil inside an aneurysm.

Each time the power supply is turned on, the unit defaults to the 1.0 mA current setting. Pressing the "Current" switch one time changes the setting to the 2.0 mA current setting; pressing a second time changes the setting to 0.5 mA; pressing a third time returns the unit to the default 1.0 mA setting. Each time the switch is pressed, the current display flashes the new current setting.

The GDC Power Supply is designed to apply a constant current through the GDC System and to detect when coil detachment has occurred. It maintains a constant current by:

1) sensing the amount of resistance to current flow through the GDC System, and
2) adjusting the voltage needed to maintain the desired current setting. It is also designed to identify subtle changes in the way current is flowing through the GDC System and to recognize those changes which indicate detachment.

Once those patterns are identified, the GDC Power Supply signals detachment and stops the flow of current through the GDC System.

Accessories Description

Accessories consist of the following:
- Two connecting cables, one black (274 cm long), the other red (152 cm long)
- Two standard 9 volt alkaline batteries

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Mr. James Leathley
Senior Regulatory Affairs Specialist
Boston Scientific/Target
Target Therapeutics
47900 Bayside Parkway
Fremont, California 94538

Re: K001083
Trade Name: Guglielmi Detachable Coil (GDC) Power Supply
Regulatory Class: III
Product Code: HCG
Dated: March 31, 2000
Received: April 4, 2000

Dear Mr. Leathley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001083

Boston Scientific
TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: K001083

Device Name: Guglielmi Detachable Coil (GDC) Power Supply

Indications for Use:

Guglielmi Detachable Coil Power Supply

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and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use _____
(Per 21 CFR 801.109)

Donna R. Lechner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001083